REMARKS

Claims 2-6, 8, 9, 11, 13, 14, 16-19, 21, 22, 24, 31-33, 35, 36 and 73-79 remain in this application.

Rejections Under 35 USC 103

Claims 2, 4-6, 8-9, 11, 13-14, 16-19, 21-22, 24, 31, 33, 35-36, and 73-79 were rejected under 35 USC 103(a) as being unpatentable over CA 2,068,366 in view of Guley et al. (US 4,309,405), Roche (US 5,075,114), Kanai et al. (US 4,868,183) and Uchida et al. (US 5,215,999). See Pages 2-12 of the Office Action. According to the Office Action,

> "CA 2,068,366 teaches a taste-masked free-flowing powder including microcapsules having a particle size of 300 pm or less that includes a core element including at least one pharmaceutically active ingredient; a substantially smooth and continuous microcapsule coating on the core element formed from a coating composition including a water insoluble polymer (page 3, lines 1-11). . . . CA 2,068,366 does not teach the second coating layer is comprised of a water soluble and/or water swellable film forming polymer and an anti-grit agent such as polyethylene oxide or polyethylene glycol, the claimed ratios, or that the non-enteric polymer is hydroxypropyl cellulose. It is for this reason Kanai et al., Uchida et al., and Guley et al. are added as secondary references. . . . Therefore, the claimed invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made because every element of the invention has been fairly suggested by the cited reference." See Pages 3-9 of the Office Action.

As argued in the previous amendment dated June 7, 2011 ("Previous Amendment"), while Kanai et al. may disclose a tablet coated with HPMC and polyethylene glycol (col. 39, lines 1-27), it does not disclose particles coated with such ingredients. The mere coating of tablets will not provide the anti-grit benefit to the underlining particles when the tablet is chewed as the tablet coating is broken upon chewing. Merely coating the outside of the tablets would not remove the gritty, sandy texture of the resulting particles after the tablet is chewed and the outside tablet coating is broken. There is no disclosure, or even suggestion, that such a coating can be used for particles, let alone particles that already have a first coating as set forth in the pending claims. Furthermore, the tablet disclosed in Kanai et al. is a swallowable tablet, in which one of ordinary skill in the art would not look to for a texture masking coating (e.g., like with a chewable tablet).

Similarly, Uchida et al. also only discloses the coating of tablets with HPMC and polyethylene glycol (col. 64, lines 1-19), not the coating of particles. As discussed above, the mere coating of tablets will not provide the anti-grit benefit to the underlining particles when the tablet is chewed as the tablet coating is broken upon chewing. Merely coating the outside of the tablets would not remove the gritty, sandy texture of the resulting particles after the tablet is chewed and the outside tablet coating is broken. There is no disclosure, or even suggestion, that such a coating can be used for particles, let alone particles that already have a first coating as set forth in the pending claims. Furthermore, as with Kanai et al., the tablet disclosed in Uchida et al. is a swallowable tablet, in which one of ordinary skill in the art would not look to for a texture masking coating (e.g., like with a chewable tablet).

In response to these arguments, the Final Office Action asserts "While tablets are not particles, the technology of film coating particle or tablets with the same compounds or combinations of compounds is well known and documented in the art, as evidenced by the teachings of Yang et al., from the previous rejection, which teach the use of a mixture of hydroxypropyl methylcellulose and polyethylene glycol as a second coating of particles." See page 10 of the Final Office Action. Applicants respectfully disagree.

First, Yang et al. is not a reference cited in the rejection. Second, assuming the Final Office Action is referring to Yang et al. (US 5,576,022), as noted in the Previous Amendment, while Yang et al. discloses pellets having an "overcoat coating" containing HPMC and polyethylene glycol in Formulation No. 40 on col. 14, these pellets are sustained release pellets as they have an "sustained coating" containing ethylcellulose. Such pellets are different from the particles of the pending application wherein the coatings do not retard the dissolution of the active ingredient. The Final Office Action does not state why one of ordinary skill in the art would look to use the overcoat coating of a sustained release pellet on the particles of the present invention. As stated in Yang et al., the purpose of the overcoat is to reduce the attrition of the sustained release coating during handling. See col. 18, lines 23-24 of Yang et al. Even assuming arguendo that one would, as stated in the Previous Amendment, the ratio of HPMC to polyethylene glycol in this pellet of Yang et al. is not within the range of 80:20 to 20:80 as recited in the pending claims of the present application.

With respect to Guley et al., the Final Office Action asserts "Guley et al. teach sustained release compositions comprising a core containing a drug, a seal coating surrounding the core, and a sugar coating surrounding the seal core. . . .Guley et al. teach the seal coating is selected

from film forming materials which is capable of substantially protecting the core during its passage from the stomach to the intestine." See Pages 5-6 of the Final Office Action. As with Kanai et al. and Uchida et al. discussed above, Guley also discloses a coated tablet, and fails to disclose, or suggest, coated particles. Further, as noted above, the two coating of Guley et al. are also different from the first coating layer and the second coating layer of the pending claims (e.g., the second coating of Guley et al is a sugar coating and fails to disclose an anti-grit agent selected from the group consisting of polyethylene oxide, polyethylene glycol, and mixtures thereof. Still further, as with Kanai et al. and Uchida et al., the tablet disclosed in Guley et al. is a swallowable tablet, in which one of ordinary skill in the art would not look to for a texture masking coating (e.g., like with a chewable tablet)..

With respect to Roche, the Final Office Action asserts "Roche teaches a medicament coating comprising a blend of cellulose acetate and hydroxypropyl cellulose. The coating provides excellent taste masking while still permitting acceptable bioavailability of the active ingredient (col. 2, lines 20-28)." See Page 6 of the Office Action. While Roche discloses a coating solution comprising cellulose acetate and hydroxypropyl cellulose, like CA 2,068,366, it fails to disclose, or suggest, the second coating layer of the pending claims.

Thus, in conclusion, none of the four cited references, alone or in combination, disclose or even suggest the particles, the method of making such particles, and the dosage forms containing such particles as recited in the pending claims. Specifically, both CA 2,068,366 and Roche fails to disclose particles containing the second coating layer as recited in the pending claims. Further, one of ordinary skill in the art would not look to combine the coated particles teachings of CA 2,068,366 or Roche with either Kanai et al., Uchida et al., or Guley et al. as these references disclose tablet coatings, not particle coatings. Further, as the tablets of Kanai et al., Uchida et al., and Guley et al. are designed to be swallowed, and not chewed, one of ordinary skill in the art would not look to such references for coating solutions to texture mask particle.

Further, as recited in Example 4 of the present application, the application of this second water-soluble layer were unexpectedly found to improve the resulting particles, as compared to the particles with only the taste-masking layer, when used in a chewable tablet. As recited in Example 4, "[b]oth tablets were found to have had a similar taste, with a very slight bitterness detected by most panelists. The tablets from Example 1 [e.g., tablets made without the water-soluble layer] were found to have had a perceptible grittiness, which ranged from 'slight' to

'obvious,' and a rough surface. By contrast, the 'texture-masked' particles of the present invention produced in accordance with Example 3 were found to have had no grittiness, a smooth texture and a 'good melt-away,' i.e. the tablet was rapidly cleared from the oral cavity with minimal chewing required." Further the use of layer was not found to retard the dissolution of the active ingredient as "100% of the acetaminophen active ingredient was released from the tablets of Example 1 and Example 3 in 45 minutes." Such an unexpected result was not taught, nor suggested, by CA 2,068,366. nor Kanai et al, Uchida et al., Roche, or Guley et al.

In response to such arguments, the Final Office Action stated "The examiner cannot determine if the purported unexpected results of "less grittiness" provided by the combination of acetaminophen, ethylcellulose, hydroxypropyl methylcellulose and polyethylene glycol 8000 is reflective of the combination of any active ingredient, any water insoluble film-forming polymer, any water soluble film-forming polymer, and any anti-grit agent, known and unknown. In addition, Applicant's independent claims are directed to particles and method of making particles and not chewable tablets, as tested in the examples." See Page 11 of the Final Office Action. Applicants again respectfully disagree.

First, as noted above, both the comparative tablet and the tablet of the claimed invention had the same first coating layer. The Example shows the unexpected benefit of adding a second coating layer to the particles, which as discussed above, is not taught nor suggested by the cited references. Further, Applicant's claims are not just directed to particles and method of making particles, but are also directed to oral dosage forms (e.g., claim 8).

Accordingly, Applicants assert that the presently claimed invention would not have been obvious to a person of ordinary skill in the art at the time of the claims invention was made in light of these references. Thus, Applicants respectfully request that this rejection under 35 USC 103(a) be withdrawn.

Conclusion

For the foregoing reasons, the present application is in condition for allowance. Accordingly, favorable reconsideration of the presently presented claims in light of the above remarks and an early Notice of Allowance are courteously solicited. If the Examiner has any comments or suggestions that could place this application in even better form, the Examiner is

requested to telephone the undersigned Attorney at the below-listed number.

The Commissioner is hereby authorized to charge any deficiency or credit any overpayment to Deposit Account No. 10-0750/MCP0231USNP/WEM.

Respectfully submitted,

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